REQUIRED SITE SOPs

The following Standard Operating Procedures are required prior to the initiation of a clinical trial. Appendix II is a sample Table of Contents that includes these as well as other policy, procedures and study information expected in a MOP.

ADMINISTRATIVE

- SOP Development
- Personnel Qualifications
- Personnel Training and Certification

REGULATORY

- Essential Documents
- Source Documents

SAFETY

- Reporting Adverse Events
- Unblinding for Safety (blinded trials)

PROTOCOL IMPLEMENTATION

- Confidential HIV Counseling and Testing Procedures

LABORATORY

- Biohazard Safety and Containment
- Laboratory Data Management and Storage
- Occupational Safety
- Specimen Acquisition, Processing, Tracking, and Storage
    - Lost, Broken, and Leaking Samples
    - Receipt and Processing all Samples
- Specimen Transport
    - Shipping Specimens Locally
    - Shipping Specimens Internationally

CLINICAL RESEARCH SITE DATA MANAGEMENT

- Facility Computer and Data Security
- Data Acqusition, Entry, and Processing
- Data Queries and Data Error Correction
- Randomization Procedures
- Data Storage and Archiving
- Expedited Reporting
- System User Account Maintenance
- Data Management Training

DATA COLLECTION AND REPORTING

- Data Acqusition, Entry, And Processing
- Data Queries and Data Error Correction
- Expedited Reporting

PHARMACY PROTOCOL SPECIFIC

- Pharmacy Operations SOPS written for a specific study agent (if needed to address specific requirements a particular study agent)
- Regimens and administration
- Protocol specific prescriptions

PHARMACY OPERATIONS SOPS

- Ordering Study Agents
- Agents Inventory Process
- Study Agents Record Keeping
- Receipt of Study Agents
- Storage of Study Agents
- Study Agents Accountability
- Preparation of Study Agents
- Labeling Study Agents for Participants
- Dispensing Study Agents
- Distribution of Study Agents to Participants
- Chain of Custody, Distribution of Study Agents Through Other Site Staff to Participants
- Disposition of Study Agents
- Maintenance of Pharmacy Equipment
- Pharmacy Quality Assurance

MONITORING

- Review and follow-up of monitoring report findings